

REMARKS

I. Introduction

The Office Action mailed May 7, 2009, has been carefully considered. The present Response is intended to be a complete response thereto and to place the case in condition for allowance.

II. Status of the Claims

Claims 1-5, 7-11 and 13-27 are pending. Claims 6 and 12 have been cancelled. Claims 15-20 have been withdrawn.

III. Summary of the Office Action

In the office action, the Examiner objects

- 1) to the specification because the abstract “does not commence of a separate sheet in accordance with 37 CFR 1.52(b)(4);”
- 2) claim 6 as being in improper dependent form for failing to further limit the subject matter of the previous claim.

The Examiner also rejects

- 1) claims 1-3 under 35 U.S.C. § 103(a) as being obvious over Blichare et al. in view of Lantz et al.;
- 2) claims 1 and 6 under 35 U.S.C. § 103(a) as being obvious over Ioulalen et al. (U.S. Patent No. 6,572,892) and Blichare et al;

- 3) claims 2-5, 8-11, 13, 14, 21, 22, and 24-27 as under 35 U.S.C. § 103(a) as being obvious over Ioulalen et al. (it is believed that the Examiner meant this to be Ioulalen in view of Blichare et al.); and
- 4) claims 1-11, 13, 21, 22-24, 26, and 27 as being obviousness-double patenting over claims 1-4, 7, 14, 15, and 19 Ioulalen et al.

IV. Argument

Applicants respectfully traverse the objections and rejections as follows:

A. The abstract is proper

The Examiner objects to the abstract because it “does not commence on a separate sheet.” Applicant files herewith a substitute abstract on a separate sheet. Accordingly, Applicants respectfully request withdrawal of the rejection.

B. The claims are proper

The Examiner objects to claim 6 as being in improper dependent form for failing to further limit the subject matter of the previous claim. The objection is moot because claim 6 has been cancelled.

C. The claimed invention would not have been obvious

Claims 1-3 stand rejected under 35 U.S.C. § 103(a) as being obvious over Blichare et al. in view of Lantz et al. Claims 1 and 6 stand rejected under 35 U.S.C. § 103(a) as being obvious

over Ioulalen et al. (U.S. Patent No. 6,572,892) and Blichare et al. Claims 2-5, 8-11, 13, 14, 21, 22, and 24-27 stand rejected under 35 U.S.C. § 103(a) as being obvious over Ioulalen et al. (it is believed that the Examiner meant this to be Ioulalen in view of Blichare et al.). Applicants respectfully traverse those grounds of rejection.

The cited references, taken alone or in combination, fail to disclose every limitation of the claimed invention. In particular, the cited references fail to disclose “an active constituent that has been eliminated from the surface of the lipidic particles” as recited in the claims.

In the Office Action, on page 7, the Examiner alleges that Blichare et al. discloses that when the medicated granules are heated to a temperature which is higher than that of the wax carrier, “the heated medicament powder sinks into the molten surface (e.g. recedes from the surface) and the formulation is allowed to cool thereby capturing the particles below the surface of the granules.” Applicants respectfully submit that this allegation ignores the complete disclosure of Blichare et al. which is reproduced below for the Examiner’s convenience:

The wax-like material is contacted with powdered medicament at a higher temperature, preferably at a temperature somewhat above the melting point of the wax-like material. Constant agitation is maintained and the powdered medicament sinks into the molten surface of the wax-like material pieces. The granules thus formed can then be tabletted, if necessary with the addition of conventional tabletting lubricants or encapsulated. Products are obtained which release the medicament at predetermined rates.

Column 1, lines 50-60. This disclosure cannot be interpreted to disclose that the active ingredient is “eliminated from the surface of the lipidic particles.” Blichare et al. discloses that “constant agitation is maintained” during the mixing of the powder medicament and the wax-like material. Thus, even though some of the powder may sink into the wax-like material, the constant agitation would allow some of the powder to remain on the surface. How much powder remains on the surface depends on several factors, such as the size and weight of the powder

particle, and the agitation rate. None of this information is available to the Examiner to determine that the powder has been “eliminated from the surface of the lipidic particles.”

The Examiner is reminded that, to rely on inherency, “the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied art.” *Ex parte Levy*, 17 USPQ2d 1461 (Bd. Pat. App. & Inter. 1990) (emphasis in original). Moreover, “extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” *In re Robertson*, 49 USPQ2d 1949, 1950-1951 (Fed. Cir. 1999) (citations omitted, emphasis added).

Here, the Examiner has failed to show that all of the process of Blichare et al. must necessarily result in the powder being “eliminated from the surface of the lipidic particles.” Applicants respectfully submit that this burden on the Examiner cannot be satisfied, because the information disclosed by Blichare et al. is not sufficient to conclude that the active ingredient must necessarily be “eliminated from the surface of the lipidic particles.”

With regard to Lantz et al., the Examiner relies on that reference to disclose “an oral pharmaceutical preparation having sustained release properties comprising substantially spherical lipid pellets having a solid medicament.” Office Action, page 6. However, because this reference fails to cure the deficiency of Blichare et al., their combination cannot render the present invention obvious.

With regard to Ioulalen et al., the Examiner specifically noted that the reference fails to “expressly discuss the formation of a compound where the active constituent has been eliminated

from the surface of the particle.” Office Action, page 11. Thus, because this reference fails to cure the deficiency of Blichare et al., their combination cannot render the present invention obvious.

Therefore, as discussed above, because the cited references do not disclose all of the claimed limitations, their combination cannot render the present invention obvious within the meaning of 35 U.S.C. § 103. Accordingly, Applicants respectfully request withdrawal of the rejection.

D. The claims are not double patented

Claims 1-11, 13, 21, 22-24, 26, and 27 stand rejected under obviousness-double patenting over claims 1-4, 7, 14, 15, and 19 Ioulalen et al. Applicants respectfully traverse the rejection.

In his rejection, the Examiner fails provide any reason why the present claims are obvious over Ioulalen et al. The Examiner merely concludes that the claims are not patentably distinct from each other without any reasons. Office Action, page 16. The Examiner even fails to refer to his obviousness rejection. Applicants respectfully remind the Examiner that the standard for a *prima facie* case of obviousness-double patenting is the same for that of obviousness under 35 U.S.C. § 103, and must employ the *Graham v. John Deere* analysis. See MPEP 804(II)(B)(1). Because the Examiner has not provide any analysis remotely in accordance with the MPEP, the Examiner has failed to carry his burden to provide a *prima facie* case.

Nevertheless, Applicants respectfully submit that the present claims are not obvious over those of Ioulalen et al., as discussed in Section IV.C. above. Accordingly, the rejection should be withdrawn.

V. Conclusion

Applicants have responded to the Office Action mailed May 7, 2009. All pending claims are now believed to be allowable and favorable action is respectfully requested.

In the event that there are any questions relating to this Amendment or to the application in general, it would be appreciated if the examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Please charge any shortage or credit any overpayment of fees to BLANK ROME LLP, Deposit Account No. 23-2185 (127137.0101). In the event that a petition for an extension of time is required to be submitted herewith and in the event that a separate petition does not accompany this response, Applicants hereby petition under 37 C.F.R. 1.136(a) for an extension of time for as many months as are required to render this submission timely.

Any fees due are authorized above.

Respectfully submitted,

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